

### **Remarks**

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Initially, applicants note that a filing receipt has not been generated and mailed to applicants. It does not appear that any of the records on PAIR contain the filing receipt. Applicants respectfully request that the U.S. Patent and Trademark Office ("PTO") mail a filing receipt with the next office action if not sooner.

Pursuant to the comments on page 2 of the outstanding office action, the claim numbering 1-18 has been maintained. Claim 19 has been identified as cancelled in view of the renumbering of claims 17-19 (to 16-18) and the proscription against using the number "19" for any new claims in the future.

Claim 1 has been amended. No new matter has been introduced by these amendments. Claims 1-18 remain pending.

The objection to claim 1 is overcome by the above amendments, and should be withdrawn.

The rejection of claims 1-18 under 35 U.S.C. § 112, second paragraph, for indefiniteness is respectfully traversed.

The PTO identified two bases of rejection: (i) omission of an essential step in claim 1; and (ii) purported indefiniteness of the language "under condition allowing" in describing the manner in which the process steps (a), (b), and (d) are carried out.

The first basis of rejection is overcome by the amendment to step (c), which clarifies that the ligand is not transferred from a first support to a second support with the one or more protein isoforms.

Applicants respectfully submit that the language "under conditions allowing" is not indefinite as it is used in steps (a), (b), and (d).

The specification makes it clear that the claimed method may be used in conjunction with many different types of protein isoforms to identify ligand(s) having binding specificity for one or more of those protein isoforms. While the examples relate to the

identification of ligands that bind an isoform of a prion protein, the claimed invention is not limited in this manner. Indeed, the description of the invention on pages 5 and 6 of the present application refers generally to target and control isoforms, and at page 7, lines 1-2, the description clearly recites that the target and control isoforms includes “isoforms of any protein having more than one structural isoform.” Examples listed at page 7, lines 3-9, of the present application include a  $\beta$ -peptide isoform as involved in Alzheimer’s disease and cerebral amyloid angiopathy, an alpha-synuclein isoform, a Tau protein isoform as involved in neurofibrillary tangles in frontal temporal dementia and Pick’s disease, a superoxide dismutase isoform, a huntingtin isoform, a human transthyretin isoform protein, as well as the prion protein isoforms.

Accordingly, the skilled technician would readily appreciate that the method of Claim 1 would be equally applicable to a wide range of different proteins having more than one structural isoform, and not only prion proteins.

Page 12, line 20, to page 14, line 19, of the present application provides details of both the first and second detectable markers and the detection steps used in the claimed method. The first and second detectable markers are defined as referring to *any entity* with which the presence of a protein isoform can be determined. When employing a detectable marker, the particular label or detectable group used to detect the isoform is not critical as long as it is compatible with the requirements of the assay being performed. The detectable label (i.e., the first or second detectable marker) can be *any* material having a detectable, physical or chemical property. Useful detectable markers include fluorescent dyes, radio labels, or enzymes. Specific examples are given on page 12, line 30, to page 13, line 6, and further examples of detectable markers are given in the first paragraph on page 14.

Page 17, line 22, to page 19, line 3, of the present application describes the use of ligands to detect and remove structural isoforms of proteins. The section is intentionally generic because there are many different types of first and second detectable markers, which could be used in the identification of a suitable ligand having binding specificity for a protein isoform in the sample. In addition, Example 1 (sections A to I) and Example 2 provided in the patent specification disclose specific details of the reagents and reaction conditions that allow formation of the complex in step (a), the generation of the first detectable signal in step (b), and the generation of the second detectable signal in step (d) of the claims method.

Hence, given that there are many different types of ligands, isoforms, and markers that could be used with the claimed method, applicants submit that it is improper for the claim language to be limited to *one* specific set of reaction conditions to allow formation of the complex in step (a), the generation of the first detectable signal in step (b), and the generation of the second detectable signal in step (d) for just *one* type of detectable marker.

The person of ordinary skill in the art would readily appreciate that the specific conditions allowing formation of the complex in step (a), generation of the first detectable signal in step (b), and generation of the second detectable signal in step (d) of Claim 1 will depend on the type of ligands, protein isoforms, and detectable markers used. Such conditions can easily be determined without undue experimentation once the ligand(s), isoform and detectable markers for performing the claimed method have been selected. Therefore, use of the term “under conditions allowing” is not indefinite.

For these reasons, the rejection of claims 1-18 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The rejection of claims 1-6, 8, 9, and 11-17 under 35 U.S.C. § 102(c) as anticipated by U.S. Patent Application Publ. No. 2004/0229280 to Hammond et al. (“Hammond I”) is respectfully traversed in view of the accompanying Declaration of Julia T. Lathrop under 37 C.F.R. § 1.131 (the “Lathrop Declaration”).

As explained in the Lathrop Declaration, the presently claimed subject matter was not disclosed in a published patent application by another filed in the United States before the invention by the applicants. That is because the invention disclosed but not claimed in Hammond I was invented by the applicants of the present application. Lathrop Declaration, ¶¶ 4,5. Ruben Carbonell, the only inventor on Hammond I who is not listed as an inventor on the present application, did not contribute to the invention of the presently claimed subject matter. Lathrop Declaration, ¶ 3.

Under these circumstances, Hammond I is not available as prior art under 35 U.S.C. § 102(c). Therefore, the rejection of claims 1-6, 8, 9, and 11-17 over Hammond I is improper and should be withdrawn.

The rejection of claim 7 under 35 U.S.C. § 103(a) for obviousness over Hammond I in view of U.S. Patent No. 4,245,064 to Drobnik et al. ("Drobnik") in view of U.S. Patent No. 7,217,507 to Hammond et al. ("Hammond II") is respectfully traversed. Because Hammond I is not available as prior art for the reasons noted above and the PTO has failed to demonstrate that the subject matter of claim 1, let alone claim 7 dependent thereon, would have been obvious over the combination of Drobnik and Hammond II, the rejection of claim 7 is improper and should be withdrawn.

The rejection of claim 10 under 35 U.S.C. § 103(a) for obviousness over Hammond I in view of U.S. Patent No. 5,989,921 to Charlton et al. ("Charlton") is respectfully traversed. Because Hammond I is not available as prior art for the reasons noted above and the PTO has failed to demonstrate that the subject matter of claim 1, let alone claim 10 dependent thereon, would have been obvious over Charlton alone, the rejection is improper and should be withdrawn.

The rejection of claim 18 under 35 U.S.C. § 103(a) for obviousness over Hammond I in view of U.S. Patent Application Publ. No. 2002/0155493 to Wang ("Wang") is respectfully traversed. Because Hammond I is not available as prior art for the reasons noted above and the PTO has failed to demonstrate that the subject matter of claim 1, let alone claim 18 dependent thereon, would have been obvious over Wang alone, the rejection is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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